IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA, EX. REL.; TIFFANY MONTCRIEFF, RELATOR; ROBERTA A. MARTINEZ, RELATOR; AND ALICIA BURNETT, RELATOR, *Plaintiffs* v. PERIPHERAL VASCULAR ASSOCIATES, P.A., *Defendant*	§ § § § § § § §	SA-17-CV-00317-XR

ORDER

On this day the Court considered six pretrial motions: Plaintiffs' motion to exclude certain opinions of a defense expert (ECF No. 80), three Defense motions to exclude the testimony of Plaintiffs' witnesses (ECF Nos. 82, 83, and 86), and cross motions for summary judgment (ECF Nos. 94 and 95). After careful consideration, the Court issues the following order.

BACKGROUND

This False Claims Act case arises out of the alleged fraudulent billing practices of Defendant Peripheral Vascular Associates, P.A. ("PVA"). The Plaintiffs ("Relators") allege that PVA, a healthcare provider, falsely billed Medicare for services it did not perform, either in whole or in part. Relators assert that PVA submitted tens of thousands of false bills, exposing PVA to millions of dollars in liability.

PVA is a full-service vascular surgery practice with multiple locations throughout San Antonio, Texas. ECF No. 94 ¶¶ 1–2.[1] PVA performs vascular ultrasounds, among other things. Vascular ultrasounds may be ordered by a PVA physician or an outside referring physician. *Id*. ¶ 2. Vascular studies have two components relevant to this case: a technical component and a professional component. *Id*. ¶ 3. In essence, the technical component is performing the ultrasound and the professional component is a physician analyzing the results of ultrasound. *Id*. When PVA performs one or both of these components, it submits a bill for reimbursement of the cost of the procedure to the appropriate payor—Medicare, an insurance company, or an uninsured patient. For the purposes of this order, only the method by which PVA bills Medicare and other federal payors is relevant.

Starting in the 1960s, shortly after Congress created Medicare, the need for a uniform system of medical billing became apparent. In response to this growing need, the American Medical Association ("AMA"), with industry input, developed the first version of the Current Procedural Terminology ("CPT") Codes. William T. Thorwarth Jr., M.D., *CPT: An Open System That Describes All That You Do*, 5 J. Am. Coll. Radiol. 535, 555–560 (2008), https://www.jacr.org/article/S1546-1440(07)00612-6/fulltext. The CPT Codes are a series of alphanumeric sequences used by healthcare providers to describe the procedures and services that they perform. These Codes are incredibly specific. For example, CPT Code 90832 describes an individual psychotherapy session that lasts 30 minutes. However, CPT Code 90834 describes an individual psychotherapy session that lasts 45 minutes. Yet another Code describes a session that

[1] Each party's motion for summary judgment includes a statement of uncontested facts that are presented in enumerated paragraphs. Any citation to a paragraph number in one of the briefs is a citation to these uncontested facts. Citations to pages of a brief are citations to disputed facts or legal argument.

lasts 60 minutes. These Codes are necessarily specific because health insurance companies reimburse a healthcare provider at a predetermined rate for each code.

In 1996, Congress passed the Health Insurance Portability and Accountability Act, which required the U.S. Department of Health and Human Services ("HHS") to adopt uniform standards of coding for electronic transactions involving healthcare information. *Id*. HHS adopted as one of the standards of coding the AMA's CPT Codes, which had undergone significant revision and updating. *Id*. In 2002, the CPT Codes formally became one of the methods by which healthcare providers must bill Medicare for medical services:

> The Secretary adopts the following maintaining organization's code sets as the standard medical data code sets . . . (a)(5) The combination of Health Care Financing Administration Common Procedure Coding System (HCPCS), as maintained and distributed by HHS, and Current Procedural Terminology, Fourth Edition (CPT–4), as maintained and distributed by the American Medical Association, for physician services and other health care services.

45 C.F.R. § 162.1002(a)(5). The CPT-4 continues to be a valid method of billing medical services to Medicare for reimbursement. *Id*. § 162.1002(c).

PVA and other healthcare providers submit bills to Medicare using an electronic version of the CMS-1500 form. ECF No. 95 ¶ 1. PVA lists a particular CPT Code on that form in order to inform Medicare that it has performed a particular procedure or service. *Id*. ¶ 3. When submitting the CMS-1500 form, a healthcare provider certifies that the claim for reimbursement is "true, accurate and complete," "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment," and that the "services on this form were medically necessary and personally furnished by me." *Id*. ¶ 2.

The technical and professional components of a vascular study can be billed separately or jointly. ECF No. 94 ¶ 3. Which provider bills a particular component of a vascular study depends on who performs the study. PVA physicians read and interpret studies performed at PVA offices

and at hospitals. *Id*. ¶ 6. When a hospital performs the technical component of a study, the hospital bills for that component. *Id* ¶ 5. When a PVA physician or registered vascular technologist performs the technical component, PVA bills for that component. *Id*. ¶ 6–7. PVA performs some vascular studies without a PVA physician seeing or treating the patient. *Id*. ¶ 15. These "Testing Only" studies occur when PVA performs the technical component of a vascular study for a different treating provider. *Id*. The technical component of a vascular study can be billed immediately after it is performed. *Id*. ¶ 8.

Once the technical component of a vascular study is complete, the professional component—a physician interpretation of a vascular study—can occur. A physician can interpret a vascular study in a number of ways: the physician can observe the ultrasound as it is performed; the physician can review printouts of the studies with the patient; and technologists can provide the physician with completed worksheets and preliminary reports depicting the results of the study. *Id*. ¶ 13.

A healthcare provider can bill Medicare for both the technical and professional components of a vascular study using a "global" CPT Code. ECF No. 95 Ex. 4. at 84. This is a standard five-digit code indicating that each component was performed. When a provider bills for just one component, it must use a two-character "modifier" that signifies that only one component has been performed. *Id*. at 181. As relevant here, a provider can append the "-TC" modifier when billing just the technical component, or the provider can use the "-26" modifier to bill for just the professional component. ECF No. 81 Ex. A at 8. Other than for a brief period in 2017, PVA billed Medicare for all vascular studies performed in its vascular laboratories using the "global" CPT Code without a modifier. ECF No. 95 ¶¶ 4–5.

PVA uses a program called Allscripts Clinical Module ("Allscripts CM") as its electronic medical records system and a program called Allscripts Practice Management ("APM") as its billing software. *Id*. ¶¶ 17, 22. A patient's medical record is contained in Allscripts CM. *Id*. ¶ 17. Any documentation of interpretations of a vascular study are contained in the patient's medical record. *Id*. ¶ 18. When a service or procedure is provided to a patient, PVA records the encounter in Allscripts CM. *Id*. ¶ 22. After the encounter is recorded, an interface software called ChargePass records it in APM, and a voucher is created for processing by PVA's coding and billing staff. *Id*. Two coders review a claim before submitting a bill to the payor. *Id*. ¶ 23.

In 2014, PVA adopted an archiving and communications system called MedStreaming. *Id*. ¶¶ 10–11. The purpose of this system was to help PVA physicians manage workflow and to create a reporting system that was easier for healthcare providers and patients to understand. *Id*. Every vascular study that PVA performs has a MedStreaming report. *Id*. ¶ 12. PVA's practices regarding its use of MedStreaming play a central role in this litigation.

Relators filed their initial Complaint under seal in April 2017. ECF No. 1. They filed their First Amended Complaint, also under seal, in December 2017. ECF No. 8. The Relators brought this action under the authority granted by 31 U.S.C. § 3730(b), which authorizes private persons to sue for violations of the False Claims Act ("FCA"), 31 U.S.C. §§3729 *et seq*, on behalf of the United States Government. They allege that PVA submitted false claims to Medicare by 1) billing for services before they were complete; and 2) billing for services that were not ordered by a physician. ECF No. 8 ¶¶ 1–3.

Relators assert that in an appropriate case, PVA follows particular steps to perform and bill Medicare for ultrasound studies: When a patient is referred to PVA, the patient is designated as "scheduled" in MedStreaming. *Id*. ¶ 28. The patient has an initial appointment with a PVA

physician, and the physician orders necessary tests. *Id*. A PVA sonographer performs the tests, the images are captured in MedStreaming, and the patient's status is updated to "acquired." *Id*. When the sonographer begins a preliminary report, the sonographer changes the status to "Ready." *Id*. When the sonographer completes the preliminary report, the information is sent to the PVA physician and the patient's status is updated to "QA." *Id*. At this point, the technical component is complete and can be billed to Medicare. *Id*. The PVA physician can then review the preliminary report and imaging and interpret the study. *Id.* Once the doctor's review is complete, the patient's status becomes "Final" and the professional component is ready to be billed. *Id.*

However, Relators allege PVA implemented a scheme of too-quick billing in 2012 designed to increase revenue. *Id*. ¶¶ 36–38. Specifically, PVA began frequently billing Medicare for both the professional and technical component before the patient's status becomes "Final"— before the PVA physician has reviewed and interpreted the study. *Id*. ¶ 29. The Relators allege that they personally witnessed PVA submit claims to Medicare after the sonographer completed a preliminary report, but before a physician had seen the report and conducted an independent interpretation. *Id*. ¶¶ 29–30. Relators also witnessed incidents where PVA billed for both the technical and professional components before the technical component was complete, and even where PVA billed for imaging that was never completed due to technical errors. *Id*. ¶¶ 31–32. Finally, Relators allege that PVA would on occasion order an ultrasound for referred patients before the patient had been seen by a PVA Physician, meaning no physician ordered the ultrasound. *Id*. ¶ 33–34.

The Relators provided notice of the lawsuit to the U.S. Government as required by 31 U.S.C. § 3730(b). The Department of Justice investigated the Relators' allegations for roughly a year. Over the course of the investigation, PVA provided thousands of pages of medical and business

records to the Government pursuant to a subpoena. ECF No. 94 ¶¶ 30–33. On November 26, 2018, the Government informed the Court of its decision to decline to intervene in Relators' case. ECF No. 20. The following day, the Court ordered that the Complaint be unsealed and served upon PVA. ECF No. 21.

On February 20, 2019, PVA moved to dismiss Relators' Complaint. ECF No. 27. The Court held a hearing on this motion on May 9, 2019, at which the Court orally granted in part and denied in part PVA's motion. Relators' False Claims Act claims survived. The parties proceeded with discovery for more than a year after the Court's order. On August 3, 2020, Relators moved to exclude certain opinions of PVA's expert witness, Melissa Scott. ECF No. 80. Later that month, PVA filed motions to exclude the testimony of three of Relators' expert witnesses: Dr. James Alexander, Robert Church Jr., and Dr. Zachary Nye, respectively. ECF Nos. 82, 83, 86. On August 21, 2020, the parties submitted their cross-motions for summary judgment. ECF Nos. 94, 95. The Government filed a Statement of Interest on September 18, 2020. ECF No. 113. The Court held a hearing on all pending motions on October 7, 2020. The Court made no rulings on the motions for summary judgment but ruled orally that any witness opinions amounting to legal conclusions would be excluded. The Court then considered the parties' motions.

DISCUSSION

I. Legal Standard

A. Motion to Exclude

Rule 702 of the Federal Rules of Evidence allows a witness "who is qualified as an expert" to testify if:

> a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

b) the testimony is based on sufficient facts or data;

c) the testimony is the product of reliable principles and methods; and

d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702. The Supreme Court's decision in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) provides the analytical framework for determining the admissibility of expert testimony. *Daubert* requires the district courts to act as "gatekeepers" to ensure expert testimony meets Rule 702's standards. *Id*. at 589. As a preliminary matter, a district court "must be assured that the proffered witness is qualified to testify by virtue of his 'knowledge, skill, experience, training, or education.'" *United States v. Cooks*, 589 F.3d 173, 179 (5th Cir. 2009) (quoting FED. R. EVID. 702). If the expert is qualified, a court must follow *Daubert*'s analytical framework to ensure "that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597.

The reliability inquiry entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and can be properly applied to the facts in issue. *Id*. at 592–93. In *Daubert*, the Supreme Court enumerated five nonexclusive factors to consider when assessing reliability: (1) whether the expert's theory can be or has been tested; (2) whether the theory has been subject to peer review and publication; (3) the known or potential rate of error of a technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) the degree to which the technique or theory has been generally accepted in the scientific community. *Id*. at 593–94; *see also Burleson v. Tex. Dep't of Crim. Just.*, 393 F. 3d 577, 584 (5th Cir. 2004). The test for determining reliability is flexible and can adapt to the particular circumstances underlying the testimony at issue. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999). The point of this inquiry "is to make certain that an expert, whether basing

testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.*

The relevance inquiry requires the Court to determine if expert testimony will "assist the trier of fact to understand the evidence or to determine a fact in issue." *Daubert*, 509 U.S. at 591. "Evidence is relevant if . . . it has any tendency to make a fact more or less probable than it would be without the evidence; and the fact is of consequence in determining the action." FED. R. EVID. 401.

In determining the admissibility of expert testimony, the district court should approach its task "with proper deference to the jury's role as the arbiter of disputes between conflicting opinions." *Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 422 (5th Cir. 1987). The party proffering expert testimony has the burden of establishing by a preponderance of the evidence that the challenged expert testimony is admissible. *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998); *see also* FED. R. EVID. 104.

B. Motion for Summary Judgment

The Court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. FED. R. CIV. P. 56. "A genuine issue of material fact exists when the evidence is such that a reasonable jury could return a verdict for the non-moving party." *Austin v. Kroger Tex., L.P.*, 864 F.3d 326, 328 (5th Cir. 2017). All facts and reasonable inferences are construed in favor of the nonmovant, and the court should not weigh evidence or make credibility findings. *Deville v. Marcantel*, 567 F.3d 156, 163–64 (5th Cir. 2009).

The party seeking summary judgment bears the initial responsibility of informing the district court of the basis for its motion. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the

movant carries its initial burden, the burden shifts to the party opposing the motion to present competent summary judgment evidence showing the existence of a genuine fact dispute. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp*., 475 U.S. 574, 586–87 (1986). The nonmoving party "must do more than simply show that there is some metaphysical doubt as to the material facts." *Id*. at 586. The nonmovant must come forward with specific facts showing that there is a genuine issue for trial. *Id.* at 587.

II. Motions to Exclude Expert Testimony

A. Relators' Motion to Exclude Portions of Melissa Scott's Report.

i. Sections 7.0 and 8.0 of Melissa Scott's Report are Improper Rebuttal Evidence.

Relators move to strike Sections 7.0 and 8.0 of the June 23, 2020 Expert Report of Melissa Scott, CPC, CHC, CHIAP as untimely. ECF No. 80 at 3. On March 27, Relators designated expert statistician Dr. Zachary Nye. *Id*. Relators served Dr. Nye's report on PVA on March 27, 2020. *Id*. Pursuant to the Court's Amended Scheduling Order, PVA had 15 days from March 27, 2020 to serve an expert rebuttal. *See* ECF No. 77. However, PVA served their rebuttal report on June 23, 2020—more than seven weeks late.

PVA correctly points out that Relators do not challenge Scott's qualifications or the reliability of her opinions. ECF No. 84 at 3. However, it responds that Scott is not a rebuttal expert as defined by FED R. CIV. P. 26(a)(2)(D)(ii). It asserts that rebuttal experts are only those whose opinions are "intended solely to contradict or rebut evidence on the same subject matter identified by another party." *Id*. (citing FED. R. CIV. P. 26(a)(2)(D)(ii)). In analyzing whether Scott is a rebuttal witness, PVA asks the Court to apply the factors laid out in *YETI Coolers, LLC v. RTIC Coolers, LLC*, 2017 WL 394511 at *2 (W.D. Tex. Jan. 27, 2017).

The *YETI Coolers* court applied three factors to determine whether an expert report is a rebuttal report: (1) whether the report is purporting to contradict or rebut expert opinions offered by the opposing party as to a claim or defense on which the opposing party has the burden of proof; (2) whether the opinions are on the same subject matter as that identified by the opposing party's expert in its Rule 26(a)(2)(B) disclosure; and (3) whether the evidence disclosed as rebuttal evidence is intended solely to contradict or rebut that evidence. *Id*. (citing *Wireless Agents, L.L.C. v. Sony Ericsson Mobile Commc'ns AB*, 2006 WL 5127278, at *2 (N.D. Tex. May 31, 2006)). An examination of these factors reveals that Sections 7.0 and 8.0 of Scott's report are rebuttal evidence.

First, the disputed Sections plainly purport to contradict or rebut the opinions offered by Dr. Nye on Relators' FCA claim. Section 7.0, entitled "Nye's Opinions," identifies Dr. Nye's conclusions and highlights Scott's contradictory opinion. ECF No. 80 Ex. A. That Section states "[a]s discussed below, Nye's calculations have a multitude of fundamental flaws and rely too heavily on Plaintiffs' assertions without independent validation of his underlying data sets." *Id*. ¶ 58. This is a direct response to Dr. Nye's opinions. Section 8.0, entitled "Analyses of Nye's Opinions and His Cited Bases for Calculations," provides an in-depth explanation of Scott's response to Dr. Nye. It begins with an overview of Dr. Nye's qualifications, and then explains how "Nye's analysis is fundamentally flawed." *Id*. ¶¶ 59–60. No reader could reasonably interpret these Sections as anything other than rebuttals to Dr. Nye's opinions.

Second, Sections 7.0 and 8.0 of Scott's report discuss the same subject matter as that identified by the Relators' expert in their Rule 26(a)(2)(B) disclosure. "[A] rebuttal witness must respond to new opinions brought out in her opponent's case in chief." *United States v. 9.345 Acres of Land*, No. CV 11-803-JJB-EWD, 2016 WL 5723665, at *3 (M.D. La. Sept. 30, 2016) (citing

Morgan v. Comm. Union Assurance Cos., 606 F.2d 554, 555–6 (5th Cir. 1979)). As discussed above, Scott's report does just that.

Third, the evidence is intended solely to contradict or rebut Dr. Nye's evidence. Not only do Sections 7.0 and 8.0 mention Dr. Nye by name, they specifically refute his opinions. These Sections offer detailed analysis of Scott's opinion of why Dr. Nye's analysis is unreliable. No other opinions are offered in these Sections. They cannot reasonably be offered to do anything but contradict or rebut Dr. Nye's testimony. The Court finds that Sections 7.0 and 8.0 of Scott's report are rebuttal evidence. Accordingly, the evidence should have been served pursuant to this Court's Amended Scheduling Order, ECF No. 77, within fifteen days of receipt of Dr. Nye's report.

ii. The Proper Remedy is to Exclude Sections 7.0 and 8.0 of Ms. Scott's Report.

After concluding that Scott's report contains untimely rebuttal evidence, the Court must determine the appropriate remedy.

> Concluding that a report is not a proper expert rebuttal report completes only the first of two steps to determine whether the Court should strike the report. The Court must also decide whether the improper rebuttal report is either substantially justified or harmless, and thus may avoid being excluded under Rule 26(a). When determining whether exclusion is appropriate, a court must consider the following factors ("the *Sierra* factors"): (1) the importance of the witness's testimony; (2) the prejudice to the opposing party of allowing the witness to testify; (3) the possibility of curing such prejudice by granting a continuance; and (4) the explanation, if any, for the party's failure to comply with the discovery order.

9.345 Acres of Land, 2016 WL 5723665, at *5 (citing *Sierra Club, Lone Star Chapter v. Cedar Point Oil Co.*, 73 F.3d 546,572 (5th Cir. 1996)).

First, it is difficult to determine the exact importance of Scott's testimony. Only Sections 7.0 and 8.0 of her report are improper. These amount to just three pages in a 37-page report, to which there is no evidentiary challenge. *See* ECF No. 83 Ex. A. The substance of Section 8.0,

which contains most of the explanation of Scott's rebuttal, asserts that there is no regulatory mandate that PVA generate a standalone report depicting a physician's interpretive findings before submitting a bill to Medicare for the professional component of a vascular study. *Id*. As discussed in Part III.B, *infra*, this premise is one of PVA's primary arguments in support of its motion for summary judgment and its opposition to Relators' motion for summary judgment. *See generally* ECF Nos. 94, 112. To that end, the argument itself is of vital importance to PVA's defense. However, as PVA asserts in its motion for summary judgment, the thrust of this argument is that PVA's actions do not constitute false claims under the FCA because it was not obliged to generate a standalone written report. This is a legal argument that can be argued by PVA's counsel without these Sections of Scott's report.

As to the second and third factors, there seems to be some prejudice to the Relators, but not much, should Scott be permitted to testify on the opinions in Sections 7.0 and 8.0. Relators argue in their reply brief that these opinions provide the foundation for Scott's further opinion that Robert Church's opinion is unreliable. ECF No. 87 at 1. They state that had they known about Scott's critiques they could have explored the underlying facts of her report during discovery. *Id*. at 2. PVA argues that there is no prejudice because Relators deposed Scott on July 23, 2020, but did not question the basis of her opinions regarding Dr. Nye's report. ECF No. 84 at 5. However, fact discovery closed on July 22, 2020. ECF No. 77. This leads the Court to consider whether additional fact discovery would remedy this dispute, but Relators assert that they have spent time and effort manually verifying discrepancies that Scott highlighted in her report. *Id*. Thus, additional fact discovery would only have limited benefit.

Fourth, PVA does not provide an explanation for its failure to comply with the Court's Amended Scheduling Order. PVA's only defense in opposition to Relators' motion is that Scott is not a rebuttal expert, an argument that the Court addressed above.

In sum, the analysis of the *Sierra* factors does not particularly help the Court resolve this dispute. It is clear that Scott's opinions are untimely, but their untimeliness does not appear to be overly prejudicial to Relators. It also does not appear that additional discovery would remedy the prejudice. On the whole, the Court concludes that the exclusion of Sections 7.0 and 8.0 of Ms. Scott's report is a fair outcome. The Court's conclusion can best be summed up by paraphrasing *Sierra Club*: "While a continuance would have given [Relators] more time to review the late disclosures, such a measure 'would neither punish [PVA] for its conduct nor deter similar behavior in the future.'" *Sierra Club, Lone Star Chapter v. Cedar Point Oil Co. Inc.*, 73 F.3d 546, 572 (5th Cir. 1996) (quoting *Bradley v. United States*, 866 F.2d 120, 125 (5th Cir.1989)). Relators' motion to exclude the testimony of Scott is granted as to Sections 7.0 and 8.0.

B. PVA's Opposed Motion to Exclude Relators' Expert Witness, Dr. James Alexander.

PVA moves to exclude the testimony and opinions of Dr. James Alexander as inadmissible under Federal Rule of Evidence ("FRE") 702. PVA argues that Relators have not demonstrated that Dr. Alexander is qualified to opine on vascular insurance claims or Medicare billing requirements, nor that his opinions are reliable. ECF No. 82 at 5.

i. Dr. Alexander is Qualified to Opine on Medicare Billing Requirements.

PVA argues that Dr. Alexander does not possess the expertise to provide opinions regarding PVA's practices or Medicare billing requirements. *Id.* at 6. It argues that Dr. Alexander's

background is in general surgery, not in vascular surgery, ultrasound studies, or medical coding. *Id*. In particular, PVA asserts that Dr. Alexander lacks the requisite knowledge to support Relators' theory of liability. As discussed in Part III.B, *infra*, one of Relators' primary theories is that PVA should have been creating a standalone report containing PVA physicians' interpretations prior to submitting a bill to Medicare for the professional component of a vascular study. This standalone report, Relators assert, could have been created in MedStreaming. According to PVA, however, Dr. Alexander has no specialized knowledge about the use of MedStreaming in clinical practice. *Id*.

Relators respond that Dr. Alexander's education, training, affiliations, and accreditations qualify him to opine on Medicare claims for diagnostic ultrasounds. ECF No. 85 at 15. After highlighting Dr. Alexander's distinguished background as a surgeon and military servicemember, Relators assert that Dr. Alexander's expertise in Medicare billing requirements comes from his role as the head Medical Director for Medicare in Texas and his experience overseeing the implementation of billing, coding, and Medicare compliance policies with Blue Cross and Blue Shield of Texas. *Id*. at 16 (citing ECF No. 82 Ex. B at 3–4). This experience, according to Relators, outweighs Dr. Alexander's lack of certification in coding. *Id*. (citing *Natchez Reg'l Med. Ctr. v. Quorum Health Res.*, LLC, 879 F. Supp. 2d 556, 577 (S.D. Miss. 2012) for the proposition that "*Daubert* demands reliability, not evidence of certification."). Lastly, Relators argue that there are hundreds of archiving and communication systems available for radiology use with similar functionalities as MedStreaming. So, it is sufficient that Dr. Alexander has worked with similar electronic databases, even if he has not worked with MedStreaming specifically. *Id*.

The Court finds that Dr. Alexander is qualified to opine on Medicare-billing best practices. The Fifth Circuit has repeatedly affirmed the qualification of experts based on the witness's work

experience in a particular field. *See, e.g.*, *United States v. Brown*, 871 F.3d 352, 357 (5th Cir. 2017) (upholding a witness's qualification in healthcare fraud case as an expert in "Medicare and the practices of medical equipment providers" largely because the witness had worked as a "Medicare claims-processing contractor" for over a decade and taught others "how to properly bill Medicare and comply with its guidelines."); *Mike Hooks Dredging Co. v Marquette Transp. Gulf-Inland*, LLC, 716 F.3d 886, 894 (5th Cir. 2013) (affirming the lower court's admission of an expert based on his experience in maritime navigation); *United States v. West*, 58 F.3d 133, 140 (5th Cir. 1995) (admitting an IRS agent as expert witness on tax evasion based on her work experience and accounting education); *Huval v. Offshore Pipelines, Inc*., 86 F.3d 454, 458 (5th Cir. 1996) ("Given [the expert']s broad, general experience in the insurance industry, we cannot say that the district court abused its discretion in qualifying him as an expert witness.").

Dr. Alexander's experience in the field of Medicare compliance justifies his qualification as an expert. Dr. Alexander has more than two decades of experience, having worked as the Associate Medical Director for the Medicare Division of Blue Cross and Blue Shield of Texas, and as the Medicare Contractor Medical Director for the State of Texas. ECF No. 82 Ex. B at 3–4. This work involved analysis of claims data for the detection of overutilization and fraud and abuse, and other issues relating to Medicare compliance and proper coding and billing practices. *Id*.; ECF No. 82-2 at 22. This expertise gives Dr. Alexander the "specialized knowledge [that] will help the trier of fact to understand the evidence." FRE 702(a).

ii. Dr. Alexander's Opinions are Reliable Under Federal Rule of Evidence 702.

PVA next argues that Dr. Alexander's opinions are not reliable. According to PVA, Dr. Alexander parrots Relators' theory that a standalone written report is required to bill for the

professional component of a vascular study when he could not provide a statute or regulation to support this argument. ECF No. 82 at 9. PVA also asserts that Dr. Alexander's opinion that compliance with accreditation guidelines is required to bill Medicare for vascular studies is unreliable because no such requirement exists. *Id*. at 10–11. PVA argues that Dr. Alexander's opinions are undercut by his own admission that PVA could bill Medicare if it simply appended a physician's interpretations in a patients' medical record, meaning a standalone report is not required. *Id*. at 11–12.

Relators respond that PVA's arguments about whether a standalone report is required to bill Medicare are misplaced in a Daubert motion and should instead be addressed in the context of a motion for summary judgment. ECF No. 85 at 18. Relators then argue that compliance with accreditation guidelines is relevant to Medicare reimbursement because the local coverage determination for the services at issue here state that "[a]ll non-invasive vascular studies must be . . . performed in an accredited vascular laboratory." *Id*. at 19 (citing Fahimi Decl. ¶ 7; Ex. F at p. 6). Finally, Relators argue that Dr. Alexander reviewed all the data that PVA provided and insisted was complete when coming to his conclusions. To the extent that PVA wishes to argue that this data was incomplete, it may argue that to the jury. *Id*. at 20 (citing Alexander Report at p. 8; Fahimi Decl. ¶ 2; Ex. A, Alexander Tr. at 145:3-5).

The Court agrees that argument on whether a standalone report is required is appropriately addressed in a motion for summary judgment, as the Court does below. *See* Part III.B, *infra*. The Court rejects the remainder of PVA's speculation arguments outright. The Court finds that PVA's objections primarily go to the weight to be given Dr. Alexander's testimony, not its admissibility. *See, e.g. Huss v. Gayden*, 571 F.3d 442, 452 (5th Cir. 2009); *Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of

proof are the traditional and appropriate means of attacking shaky but admissible evidence."). The crux of PVA's reliability argument is that none of Relators' experts can proffer any legal support for Relators' assertion that PVA billed for the professional component of vascular studies before the professional component was complete. PVA asserts that Dr. Alexander "attempt[s] to shoehorn accreditation requirements into a CMS condition of payment," or that "Dr. Alexander relied on incomplete and inaccurate information to support his opinion." ECF No. 82 at 10–11. But as discussed below, the Court does not rely on the experts' opinions alone in concluding that billing Medicare for the professional component of a vascular study before generating a written report can constitute a false claim. *See* Part III.B, *infra*.

The Court concludes that PVA's argument that Dr. Alexander's opinions are unreliable is merely a reiteration of its substantive legal argument couched in terms of an evidentiary objection and does not justify striking his testimony. Nonetheless, for the reasons discussed below, the Court disagrees with PVA's characterization of the types of fraud that can constitute a False Claims Act violation. The Court carefully weighed PVA's arguments and evidence against Relators' allegations and found Dr. Alexander's opinions reliable and helpful to the extent explained below. Any evidence provided by Relators that was not likely to be admissible, was unreliable, or was irrelevant was not considered by the Court. The Court declines to strike Dr. Alexander's testimony as unreliable.

iii. Dr. Alexander's "Medical Necessity" Opinion is not Misleading.

Dr. Alexander makes a distinction between "regulatory medical necessity" and "clinical medical necessity." ECF No. 82-3 at 111:9–112:22. PVA argues that this is a fictitious distinction that will only mislead the jury. ECF No. 82 at 12–14. Relators respond that Medicare requires that

charged services be "reasonable and necessary," and Dr. Alexander's testimony relates to the industry understanding of that phrase.

The Court need not devote a lengthy analysis to this issue. Dr. Alexander's first opinion is that "incomplete services (in effect, services not rendered) cannot be considered medically necessary within Medicare or other payer requirements." ECF No. 82-2 at 11. He bases this opinion on the text of the Social Security Act, which states "no payment may be made under part A or part B for any expenses incurred for items or services . . . not reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). Chapter 3 of the Medicare Program Integrity Manual goes on to state that a service is considered "reasonable and necessary" if it meets certain criteria, including whether the service is "[f]urnished in accordance with accepted standards of medical practice." ECF No. 82-2 at 12–13. It is certainly not misleading for a physician and Medicare compliance expert to opine on whether these criteria are met in a given case. Further, Dr. Alexander's interpretation of "medical necessity" has been accepted before in this Circuit. *See Waldmann v. Fulp*, 259 F. Supp. 3d 579, 591 (S.D. Tex. 2016) (stating in an FCA case "[t]he Court considers Dr. Alexander's statements are an axiom: the performance of surgeries by an untrained, unsupervised, under-qualified scrub technician is neither 'medically reasonable' nor 'medically necessary' under these circumstances. No further discussion on this issue is merited."). The Court sees no reason to exclude this testimony.

iv. Dr. Alexander's Remaining Opinions are Permissible.

PVA makes several additional arguments: that Dr. Alexander's opinion that billing Medicare for the professional component of a vascular study before a standalone report has been created implicates patient safety is speculation, ECF No. 82 at 14–6; that Dr. Alexander's opinion that PVA physicians likely did not actually review vascular studies is baseless, ECF No. 82 at 16–

17; and that the documents that Dr. Alexander reviewed are not sufficient to support his conclusions, ECF No. 82 at 17–18.

First, the Court need not rule on whether Dr. Alexander's patient safety opinion is permissible at this juncture. Relators respond to PVA by conceding that this opinion will likely be unnecessary because Relators do not bear the burden of proving patient harm. ECF No. 85 at 21. Relators anticipate that PVA will argue that Medicare fraud is a "victimless crime" and plan to elicit Dr. Alexander's opinion to counter that argument. *Id*. The Court declines to rule on the admissibility of evidence that may not even arise at trial. Unless and until the issue is renewed in a motion in limine before trial, the Court will take the parties' arguments under advisement.

Second, Dr. Alexander's opinion that PVA physicians likely did not review vascular studies is relevant to the Relators' case. As discussed in Part III.D, *infra*, Relators must prove that PVA knowingly submitted false claims to Medicare. PVA argues that this opinion should still be excluded because Dr. Alexander has no experience with MedStreaming or in interpreting vascular studies. ECF No. 82 at 16. Relators respond that another expert, Dr. Nye, will present evidence that over 25% of PVA's reports were signed within five seconds of one another, and that Relators should be permitted to rebut PVA's argument that this practice was above-board. ECF No. 85 at 22.

The Court finds that this opinion is permissible. As discussed, Dr. Alexander is qualified to opine on Medicare compliance and billing best practices. This includes opinions relating to the expected use of archiving and communication systems like MedStreaming. Surely a former Medical Officer for Medicare in the State of Texas can testify as to how Medicare would view data showing rapid-succession signatures. Further, a Medicare compliance expert with experience working with archiving and communications systems is free to testify that, in his experience, it is

unlikely that a physician could interpret vascular studies within five seconds of one another. To the extent that PVA wished to argue that MedStreaming is a unique system that permits this type of speedy signing, it is free to do so.

Third, Dr. Alexander relies on sufficient evidence such that his opinion may be presented to the jury. FRE 702(b) requires a court to determine whether an expert's testimony "is based on sufficient facts or data." As mentioned, the Court weighed Dr. Alexander's report in conjunction with the evidence presented by Relators and PVA. To the extent that PVA argues that Dr. Alexander relies on insufficient data to support his conclusions, that goes to the weight of his testimony and not its admissibility.

In sum, the Court denies PVA's motion to exclude the testimony of Dr. James Alexander. As stated in open court, any legal conclusions proffered by the experts are excluded and were not relied upon by the Court in coming to its conclusions in this opinion.

C. PVA's Opposed Motion to Exclude Relators' Expert Witness, Robert Church, Jr.

PVA next moves to exclude the testimony of Relators' expert witness Robert D. Church, Jr. under FRE 702 and 403. ECF No. 83. Specifically, PVA challenges Church's opinions regarding the requirements for billing the professional and technical components of a vascular study globally and whether PVA violated its own compliance plan. *Id*. at 3–4.

i. Church is qualified to opine on Medicare billing requirements.

PVA argues that Church is not qualified to opine on Medicare billing requirements because he has no specialized expertise in coding, billing, or Medicare conditions of payment. *Id*. at 6. This is because Church is not a certified professional coder and has no special certification in any type of coding or billing. *Id.* PVA asserts that Church's lack of qualifications manifests itself in the

unreliable bases for his opinions—Church relies on internet sources and blog posts to "obfuscate his unfamiliarity with basic Medicare coding and billing requirements." *Id*. at 7.

PVA cites to Church's deposition testimony, in which Church says he has never used MedStreaming, is not familiar with its capabilities, and was not retained to determine whether particular MedStreaming reports satisfied the applicable billing requirements. *Id.* at 8 (citing ECF No. 83 Ex. C, Tr. 94:7–95:20, 108:20–109:3). PVA argues that, while Church has experience in accounting, his experience with billing and coding is insufficient to qualify him to opine on Medicare fraud issues. *Id*. (citing ECF No. 83 Ex. C, Tr. 19:7–38:15). For example, even though he founded Health Care Economics, a company that provides healthcare business management services to healthcare providers, he was not involved in the group focused on healthcare billing and coding. *Id*. (citing ECF No. 83 Ex. C, Tr. 37:4–38:11).

Relators respond that PVA focuses too much on Church's accounting experience and ignores his other experience that is relevant to PVA's alleged false billings. ECF No. 88 at 17. They point out that Church has worked as an expert in healthcare lawsuits and worked for many years in the healthcare billing industry, and has special experience working for state Medicaid divisions educating the divisions about fraud and abuse. *Id*. (citing ECF No. 88 Ex. 1, Church Dep. Tr. at 22:9–18, 24:5–20, 25:6–19). Relators further cite to Church's experience providing coding services through his company Health Care Economics, which involved taking meetings, engaging in discussions, and advising businesses based on the submission of coding and billing—more than simply running the company, as PVA alleged. *Id*. (citing ECF No. 88 Ex. 1, Church Dep. Tr. at 36:20–37:15, 38:4-11).

The Court finds that Church is qualified to opine on Medicare billing requirements. First, PVA's argument that an expert is unqualified simply because he is unfamiliar with MedStreaming

is rejected for the same reason set forth in Section II.B *supra*. PVA is free to argue at trial that unfamiliarity with MedStreaming impugns an expert's credibility. Second, the Court finds that Church has experience that gives him "specialized knowledge [that] will help the trier of fact to understand the evidence." FRE 702(a). Church has experience reviewing and consulting on matters related to healthcare fraud that make him more knowledgeable than the typical layperson. For example, Church founded two companies that conduct investigations in fraud cases, including in *qui tam* lawsuits such as this. ECF No. 83-2. Church was the vice president of compliance and fraud for Gateway Health Plan, and in that capacity consulted with eight states to develop fraud, waste, and abuse teams. His C.V. highlights extensive Medicare and Medicaid experience, including his work managing fraud investigations and coordination with CMS for the Alabama Medicaid Agency and the Mississippi Division of Medicaid. *Id*. The Fifth Circuit has upheld the qualification of experts based on similar experience. *See* Part II.B.i (collecting cases).

ii. Church's opinions are not unreliable.

PVA next argues that Church's medical necessity opinions are unreliable because he is not a physician. ECF No. 83 at 10. It asserts that Church has had no medical training and could not identify any patient in the records he reviewed for whom a procedure was not medically necessary. *Id*. (citing ECF No. 83 Ex. C, Tr. 55:9–57:14). It goes on to assert that he "attempts to rescue his opinion by creating fictional concepts of medical necessity." *Id*. at 11. According to PVA, Church testified that if a study was not documented in an appropriate manner, it would not meet the definition of "medical necessity." But, PVA argues, this is not based on any legal or medical definition and is simply parroting the Relators' case. PVA further argues Church's only support for this opinion is a blog post from the American Association of Professional Coders. *Id*. at 11–

12. PVA asserts that his opinions cannot be reliable because he does not cite any statute or regulation supporting his opinions. *Id*. 12–14.

Relators disagree, citing the difficulty in measuring the reliability inherent in the "soft sciences" like Church's expertise. ECF No. 88 at 18–19. Relators assert that Church cites to numerous authorities supporting his opinions and methodology in his report, and that these sources all agree that providers cannot bill for incomplete services. *Id*. at 19. Relators further argue that even though PVA ignores these numerous sources, its fixation on a "blog" is misplaced because there is nothing improper about finding industry sources online that support an expert's theory. *Id*. at 19–20. That is, "PVA fails to acknowledge the numerous pages of testimony where Mr. Church repeatedly indicated that CMS-1500, ICAVL, and ACR all speak to 'abiding by what Medicare requires in terms of documentation to bill a service.'" *Id*. at 20 (citing ECF No. 88 Ex. 1 Dep. Tr. at 74:3–77:12).

As with its argument that Dr. Alexander's opinions are unreliable, outlined above, the theme underlying PVA's argument here is that it was not required to generate a standalone written report containing a physician's interpretation before billing Medicare for the professional component of a vascular study. The Court again rejects that argument as a ground for excluding expert testimony. PVA's argument that no regulation or statute supports Relators' theory of liability is noted and addressed below.

The Court finds that Church has relied on sufficient evidence such that his opinion may be presented to the jury. FRE 702(b) requires a court to determine whether an expert's testimony "is based on sufficient facts or data." In his report, Church highlights the numerous industry publications that he relied upon, including publications by CMS and other governmental agencies. ECF No. 83-2. Additionally, Church states that he relied upon documents provided by PVA,

including PVA's own compliance policies and procedures. *Id*. Any argument that this evidence was insufficient is best addressed on cross-examination. *Huss*, 571 F.3d at 452; *Daubert*, 509 U.S. at 596. The Court also rejects PVA's "medical necessity" arguments for the reasons stated in Part II.B.iii of this Opinion.

iii. PVA's remaining objections.

PVA next argues that Church's opinion that PVA submitted false claims in violation of federal law should be excluded because this opinion is derivative of the testimony of Relators' expert witness, Dr. Zachary Nye. ECF No. 83 at 14. PVA also asserts that Church's opinions are a "red herring" and speculative because there is no federal requirement that a healthcare provider have a regulatory compliance plan. *Id*. at 17–18. Relators respond that there is nothing improper about courts admitting testimony that relies on the data provided by other experts. ECF No. 88 at 22. Relators also assert that Church's opinions relating to PVA's compliance with its own plan are relevant to the scienter element of a False Claims Act claim. *Id*. at 24–25.

The Court finds that PVA's objections do not warrant exclusion. "The Fifth Circuit has [stated] that, in determining the admissibility of expert testimony, a district court must defer to 'the jury's role as the proper arbiter of disputes between conflicting opinions." *Scordill v. Louisville Ladder Grp., L.L.C*, No. Civ. 02-2565, 2003 WL 22427981 at *3 (E.D. La. Oct. 24, 2003) (internal citations omitted). "As a general rule, questions related to the bases and sources of an expert's opinions affect the weight to be assigned that opinion rather than its admissibility and should be left for the jury's consideration." *United States v. 14.3 Acres of Land More Or Less Situated in Lefore County, Ms.*, 80 F.3d 1074, 1077 (5th Cir. 1996). Likewise, experts are permitted to rely on inadmissible evidence as long as the evidence is "reasonably relied upon by experts in the particular field." FED .R. EVID. 703. This includes reliance on reports provided by other experts.

See e.g., Monsanto Co. v. David, 516 F.3d 1009, 1015 (Fed. Cir. 2008) ("Likewise, numerous courts have held that reliance on scientific test results prepared by others may constitute the type of evidence that is reasonably relied upon by experts for purposes of Rule of Evidence 703."). That Church relies on a report generated by Dr. Nye is not grounds for exclusion. To the extent that PVA asserts that there is "too great an analytical gap" between Church's opinions and the bases for those opinions, it is free to argue as much to the jury.

In sum, the Court denies PVA's motion to exclude the testimony of Robert Church, Jr. As stated in open court, any legal conclusions proffered by the experts are excluded and were not relied upon by the Court in coming to its conclusions in this opinion.

D. PVA's Opposed Motion to Exclude Relators' Expert Witness, Dr. Zachary Nye.

PVA's final expert challenge is to exclude the testimony of Relators' expert witness Dr. Zachary Nye under FRE 702, or in the alternative, to exclude two of Dr. Nye's supplemental reports as non-compliant with Rule 26 of the Federal Rules of Civil Procedure. ECF No. 86. Specifically, PVA argues that Dr. Nye's reports are unreliable because they are based on "disingenuous and simplistic guidelines offered by Relators' counsel," that Dr. Nye's supplemental reports are based on information available at the time of Dr. Nye's initial report, and that Dr. Nye's opinions are speculative. *Id*. at 1–2.

i. Dr. Nye relied on sufficient data to form his opinions.

PVA asserts that Dr. Nye's opinions are unreliable under FRE 702 because he has no experience in the healthcare industry and bases his opinions on data provided by Relators' counsel. *Id*. at 6. PVA cites to an excerpt of Dr. Nye's deposition in which he states that he did not verify that the medical records and billing system data provided by Relators' counsel was accurate. *Id*.

(citing ECF No. 86 Ex. D, Tr. 38:13-24). Further, PVA argues that Dr. Nye's opinions do not assist the trier of fact because he does not distinguish between the technical and professional components of a global claim submitted for reimbursement, thus failing to distinguish the portions of the global claim that was allegedly improperly paid from that which was properly paid. *Id*. at 7.

Relators respond that it is disingenuous of PVA to argue that Dr. Nye merely relied on data provided by Relators' counsel because the data was actually provided by PVA. ECF No. 91 at 4. Dr. Nye analyzed data from PVA's Allscripts and MedStreaming databases, ultimately amounting to over 2.5 million lines of PVA's raw data. *Id*. at 14. Dr. Nye then performed relatively simple calculations, flagging data charges with a posting date that was prior to the finalization date as "false billings" and sorting those charges in a variety of manners. *Id*. Additionally, Relators respond to PVA's argument that Dr. Nye improperly included non-federal payors in his analysis by pointing to Exhibits 4d and 6d in his initial report, which breaks down his findings by payor. *Id*. at 17.

The Court finds that Dr. Nye relied on sufficient data to form his opinions. Certainly, a Court should decline to admit opinions that are based on an insufficient quantum of data. But "[w]here an expert otherwise reliably utilizes scientific methods to reach a conclusion, lack of textual support may 'go to the weight, not the admissibility' of the expert's testimony." *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 354 (5th Cir. 2007) (citing *Fed. Deposit Ins. Corp. v. Suna Assocs., Inc.*, 80 F.3d 681, 687 (2d Cir.1996) (discussing *Daubert* factors)). PVA does not argue that the calculations performed by Dr. Nye are themselves unreliable, or that Dr. Nye is unqualified to perform those calculations. PVA's objection is that Dr. Nye does not have the medical expertise to verify the veracity of the records provided by PVA. This argument goes to the weight of Dr. Nye's opinion, and is not grounds for exclusion.

The same is true for PVA's argument that Dr. Nye fails to distinguish between the professional and technical components of a vascular study in his reports. Whether Dr. Nye failed to do so does not undercut the sufficiency of the data he relied upon. PVA's concerns are properly addressed on cross-examination or the presentation of refuting evidence.

ii. Dr. Nye's supplemental reports are timely.

PVA next argues that Dr. Nye's supplemental reports, produced July 8, 2020 and July 30, 2020, were untimely under FED. R. CIV. P. 26(a)(2)(B). ECF No. 86 at 9. It asserts that "Dr. Nye's supplemental reports do not relate to new disclosures, but instead offer entirely new opinions and calculations based on data and information available at the time of his Initial Report on March 27, 2020." *Id*. PVA cites to Dr. Nye's deposition, in which he admits he did not perform certain calculations absent from his initial report but present in his supplemental reports until asked by Relators. *Id*. at 9–10.

Relators respond that Dr. Nye's supplemental reports are timely because PVA's original production of data was incomplete. ECF No. 91 at 18. PVA originally served responses to Relators Requests for Production of Documents on August 22, 2019 and January 7, 2020, and Relators moved to compel the production of more complete data on April 2, 2020. *Id*. PVA eventually provided a complete production on June 25, 2020, three months after Dr. Nye's initial report. *Id*. (citing Berger Decl. ¶ 4). Relators assert that Dr. Nye's supplemental reports were based on new data, and thus not untimely under Rule 26. Relators also argue that PVA does not point to any prejudice that it would suffer because of Dr. Nye's supplemental reports.

FED. R. CIV. P. 37(c) states "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial unless the failure was substantially justified

or harmless." *Torres v. City of San Antonio*, No. SA:14–CV–555–DAE, 2014 WL 7339122, at *1 (W.D. Tex. Dec. 23, 2014). Rule 26(e) requires supplementation of an expert report "in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect." Here, it appears Dr. Nye's supplemental reports were provided to PVA within one month of Relators' receiving PVA's complete data production. Insofar as Dr. Nye's initial report was based on partial data provided by PVA, his incomplete report was supplemented and corrected as required by Rule 26(e). Even if it was untimely, PVA does not state how the untimeliness resulted in prejudice. *See generally*, ECF No. 103. PVA was able to take Dr. Nye's deposition after receipt of his supplemental reports and has not identified any other way in which it was harmed by the disclosure. Accordingly, the Court declines to exclude Dr. Nye's supplemental reports as untimely.

iii. PVA's remaining arguments.

PVA's final arguments are that Dr. Nye's opinions reflecting subjective assessments of the data should be excluded because he does not have the necessary expertise to form those opinions, and that his opinions regarding E/M claims are unsupported. ECF No. 86 at 11–12. PVA takes particular umbrage with Dr. Nye's use of the phrase "false billings" throughout his report, asserting that such phraseology will mislead the jury. *Id*. at 11. PVA also argues that any calculations regarding E/M services are irrelevant because Relators do not claim that E/M services were fraudulently billed. *Id*. at 12.

Relators respond that Dr. Nye will freely admit his "use of the term 'False Billings' is based solely on his understanding of Relators' theory of the case, and not his independent judgment." ECF No. 91 at 19. Relators also assert that Dr. Nye's calculations regarding E/M services are

relevant to Relators' theory that PVA engaged in fraudulent conduct by improperly "double billing" for both global vascular studies and E/M visits. *Id*.

The Court finds PVA's remaining arguments unavailing. The risk of prejudice from the use of the phrase "false billings," if any, is minimal and easily remediable through cross examination. To the extent that PVA disagrees that it falsely billed, that is a legal argument against Relators' theory of the case and is addressed below. The same is true of Dr. Nye's calculations regarding E/M services. The relevance of the E/M services provided by PVA is addressed extensively below, and is not grounds for excluding Dr. Nye's report.

In sum, the Court denies PVA's motion to exclude the testimony of Dr. Zachary Nye. As stated in open court, any legal conclusions proffered by the experts are excluded and were not relied upon by the Court in coming to its conclusions in this opinion.

III. Cross-Motions for Summary Judgment

On August 21, 2020 the Parties filed cross-motions for summary judgment. ECF No. 94, 95. Although the parties filed separate motions, there is significant overlap in the arguments made in the motions and accompanying responses. The Relators' response to PVA's motion largely imitates their own motion, and PVA's response to the Relators' motion largely imitates its own motion. Accordingly, the Court will address the motions together.

A. False Claims Act Liability

The False Claims Act ("FCA") prohibits false and fraudulent claims for reimbursement to the federal government. An entity violates the FCA when it:

1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government a false or fraudulent claim for payment or approval;

2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; [or]

3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

United States ex rel. Longhi v. United States, 575 F.3d 458, 467 (5th Cir. 2009) (citing 31 U.S.C. § 3729(a) (2015)). The FCA attaches liability "not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment." *Id*. (citing *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999)).

The FCA applies to those who "knowingly assist[] in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government." *Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975). A person acts "knowingly" with respect to information if the person "has actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b).

"In addition to the statutory requirements, courts have held that a false or fraudulent claim violates the FCA only if the misrepresentation it contains is material." *Waldmann*, 259 F. Supp. 3d at 589–90 (citing *Longhi*, 575 F.3d at 467; *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997); *Universal Health Servs., Inc. v. United States*, 136 S.Ct. 1989, 2002, 195 L.Ed.2d 348 (2016)). The materiality requirement is a "rigorous" one. *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 1996, 195 L. Ed. 2d 348 (2016).

The Fifth Circuit has adopted a concise test for liability under the FCA. To succeed on a claim for violation of the FCA, the Government or relator must prove:

1) there was a false statement or fraudulent course of conduct;

2) made or carried out with the requisite scienter;

3) that was material; and

4) that caused the government to pay out money or to forfeit moneys due (*i.e.*, that involved a claim).

Longhi, 575 F.3d at 467.

B. Relators have proven the existence of a fraudulent course of conduct.

The FCA is not meant to punish every type of fraud committed against the government. *See United States v. McNinch*, 356 U.S. 595, 599 (1958). "The [FCA] attaches liability, not to the underlying fraudulent activity, but to the 'claim for payment.'" *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266–67 (9th Cir. 1996). "The courts have held that a claim may be false or fraudulent under the FCA because it includes a certification of compliance with a federal statute, regulation, or contract that is a prerequisite to obtaining the government benefit." *U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 765 (S.D. Tex. 2010) (collecting cases).

A claim may be "false" under the FCA if it is either "factually false" or "legally false." *Id.* "Factually false" claims involve "an incorrect description of goods or services or a request for reimbursement for goods or services never provided." *Bennett*, 747 F. Supp. 2d at 765. "Alternatively, legally false claims arise when a party that submits claims to the government affirmatively certifies compliance with a statute or regulation and the certification is a material condition to receiving a government benefit." *Waldmann v. Fulp*, 259 F. Supp. 3d 579, 590 (S.D. Tex. 2016) (internal citation omitted).

Relators argue that PVA used CPT Codes that misrepresented the services provided on a bill to Medicare. ECF No. 95 at 11. The crux of Relators' allegation is that PVA billed for ultrasound services using a 5-digit "global" CPT Code, which indicates that PVA has performed both the technical component and professional component of a vascular study, before the professional component was completed. *See* ECF No. 95-3 Ex. 1 at 38–39. According to Relators,

the CPT Codes are the only tool that PVA used to receive reimbursement from Medicare. To use these Codes, PVA had to certify that they accurately describe the services rendered by PVA. Thus, using the wrong CPT Codes "could have influenced the government's pay decision." ECF No. 95 at 31–33. Moreover, Medicare makes clear that it considers billing for services not rendered and naming the wrong provider as quintessential examples of fraud. *Id*.

Relators identify three distinct tranches of false claims that PVA made: 1) the "Testing Only" patient tranche; 2) the "Double Billing" tranche; and 3) the "Wrong Provider" tranche. Each of these is discussed in turn.

Relators describe the Testing Only tranche as follows: PVA often receives referrals from non-PVA healthcare providers to perform vascular studies. ECF No. 95 ¶ 8 (citing ECF No. 95 Ex. 10, Hembling Dep. Tr. at 32:20-33:11; ECF No. 95 Ex. 3, Gilpin Dep. Tr. at 57:15-23; ECF No. 95 Exs. 54, 75–196). When a patient is referred to PVA only for a vascular study, PVA does not perform Evaluation, Management, or Treatment Services ("E/M Services"). *Id*. ¶ 9. For these patients, there are no encounter notes in the patient's medical record in Allscripts CM. *Id*. ¶ 10 (citing ECF No. 95 Ex. 2, Burrow Dep. Tr. at 49:16-50:18; ECF No. 95 Exs. 53, 74–195). Accordingly, "there is nowhere besides a MedStreaming report that a PVA physician's interpretations could appear." *Id*. at 14 (citing ECF No. 95 Ex. 1, Alsabrook Dep. Tr., at 94:2-94:16; ECF No. 95 Ex. 10, Hembling Dep. Tr. at 32:20-33:11; ECF No. 95 Ex. 2, Burrow Dep. Tr. at 29:24-30:9; ECF No. 95 Exs. 53, 74–195). But PVA submitted 11,728 charges to Medicare for which no E/M Services took place and no MedStreaming report was generated. *Id*. at 15 (citing ECF No. 95 Ex. 201, Dr. Nye 2nd Supp. Report at Exs. 10a & 10b; ECF No. 95 Ex. 200, Nye Supp. Report, at Ex. 2). Relators assert that all of these claims are false because PVA billed

Medicare before completing the professional component of a vascular study, which includes creating a written report with the physician's interpretations. ECF No. 95 at 30.

Relators describe the Double Billing tranche as follows: The remainder of PVA's false charges involved PVA's own patients. For these patients, PVA physicians would visit with a patient to provide E/M Services and would then order a vascular study to be conducted on the same day. *Id*. at 15. Like the patients in the Testing Only tranche, Relators argue that no MedStreaming report was generated reflecting the PVA physicians' interpretations of vascular studies. *Id*. at 15–16. Although PVA argues that the physicians' interpretations are found in the Allscripts CM E/M Services patient note, Relators assert that the CPT definitions explicitly prohibit billing for both E/M Services and a vascular study without a separate, written report containing the physician's interpretations. *Id*. at 16 (citing App. No. 42; ECF No. 95 Ex. 45 at 6). In particular, Relators point out that the CPT Manual states:

> The actual performance and/or interpretation of diagnostic tests/studies ordered during a patient encounter are not included in the levels of E/M services. Physician performance of diagnostic tests/studies for which specific CPT® codes are available may be reported separately, in addition to the appropriate E/M code. The physician's interpretation of the results of diagnostic tests/studies (i.e., professional component) *with preparation of a separate distinctly identifiable signed written report* may also be reported separately, using the appropriate CPT® code with modifier 26 appended.

ECF No. 95, Ex. 45, at p. 6 (emphasis added).

The Wrong Provider tranche apparently overlaps with the prior tranches. This tranche does not need as much explanation. Relators simply allege that PVA submitted bills to Medicare representing the wrong "rendering" physician. ECF No. 95 at 31. This happened, Relators allege, because PVA utilized for a period of time a "pool" rendering system under which any PVA physician could review and sign MedStreaming reports in quick succession regardless of whether

that physician performed the interpretation. ECF No. 95 App. No. 18. In total, Relators assert that PVA submitted 1,690 claims that contained the wrong physician's signature. ECF No. 95 at 31.

PVA argues that the conduct alleged by Relators does not rise to the level of falsehood needed to constitute a violation of the False Claims Act. ECF No. 94 at 10–11. PVA asserts that "Medicare does not require a special report to bill for vascular studies. No statute, federal healthcare program regulation, rule, or even non-binding guidance requires a MedStreaming report or any other specialized report." *Id.* at 11. The crux of PVA's argument is that the CPT Manual is guidance that does not have the force of a regulatory requirement. ECF No. 112 at 8. According to PVA, *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1813 (2019) commands that sub-regulatory guidance cannot serve as the basis of an FCA violation and should therefore control here.

It does not. *Allina* established a rule that the government cannot retroactively change the method by which it calculates how much to reimburse for submitted claims without going through the notice and comment procedure set out by the Administrative Procedure Act. In that case, HHS revealed a change of policy on its website that retroactively reduced payments to hospitals. The government had, without notice and comment, changed how it calculated a hospital's "Medicare fraction"—the proportion of care that a hospital provides to Medicare patients that is provided to low-income Medicare patients. The fraction's denominator is the time the hospital spent caring for patients who were "entitled to benefits under" Medicare Part A. The numerator is the time the hospital spent caring for Part-A-entitled patients who were also entitled to income support payments under the Social Security Act. 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I). The bigger the fraction, the bigger the payment. *Allina*, 139 S. Ct. at 1809. After Medicare Part C was created, HHS wanted to include Part C patients in the calculation of the Medicare Fraction, but challenges to a proposed rule permitting that calculation were pending. So, in 2015 the Agency decided to

post online its calculations for the 2012 Medicare fractions for 3,500 hospitals nationwide including Part C patients. This resulted in the loss of millions of dollars for the hospitals. *Id*. at 1810. Our case is distinguishable because no substantive requirements or calculations of payments have been altered. The question is whether PVA was truthful when it billed the Global CPT Code for a vascular study.

At this point it is important to clarify what the alleged fraud actually is. Throughout its extensive briefing, PVA repeatedly asserts that for a claim to constitute actionable fraud, it must violate some legal requirement set forth by Congress or HHS. *See* ECF No. 112 at 8 ("There is no federal healthcare program statute, regulation, rule, or even non-binding guidance requiring a MedStreaming report or any other separate, stand-alone report to bill for a vascular study."); *see also* ECF No. 112 at 8, 10, 11, 15, 17; ECF No. 94 at 11, 13, 15, 16. This is not what Relators assert. Certainly, PVA is correct that violating a legal condition of payment set forth by statute or regulation may be grounds for FCA liability. But that is not the sole basis by which a healthcare provider can violate the FCA.

Relators' theory of liability is that when PVA billed Medicare by using the global CPT Codes, it was representing that it had completed both the technical and professional components of a vascular study, including the generation of a written report reflecting the physicians' interpretations. ECF No. 95 at 30. That is, PVA billed Medicare for services it had not rendered by failing to complete the professional component. Relators' assertion is that PVA violated the FCA itself. It is undisputed that the use of the Global CPT Code on the CMS-1500 form certifies that a written report including a physician's interpretations of a vascular study have been completed. *See* ECF No. 95 Ex. 1; ECF No. 112 Ex. 1. The question is whether submitting a global CPT Code without creating a written report renders that certification "false" under the FCA.

45 C.F.R. § 162.1002 states that "[t]he Secretary adopts the following maintaining organization's code sets as the standard medical data code sets . . . (a)(5) The combination of Health Care Financing Administration Common Procedure Coding System (HCPCS), as maintained and distributed by HHS, and Current Procedural Terminology, Fourth Edition (CPT–4), as maintained and distributed by the American Medical Association, for physician services and other health care services." Merriam-Webster's dictionary defines "maintain" as (1) to keep in an existing state (as of repair, efficiency, or validity): preserve from failure or decline; (2) to sustain against opposition or danger: uphold and defend; (3) to continue or persevere in: carry on, keep up; (4) to support or provide for; sustain; or (5) to affirm in or as if in argument. As an initial matter, the dictionary definition of "maintain" seems to indicate that the AMA is tasked with keeping the codes up to date. This means that the AMA is tasked with defining the services that are encompassed within a particular CPT Code. That is, the AMA is the organization that decides what it means to submit a given CPT Code to Medicare for billing. Thus, it is imperative that a healthcare provider knows exactly what a particular CPT Code means before certifying that it has completed the services described by that Code.

This appears to be understood by the AMA. The CPT Codes occasionally require cross-referencing before billing. For example, CPT Code 67225 (photodynamic therapy of a second eye) must be billed along with CPT Code 67221 (photodynamic therapy of just one eye). MEDICAL BILLING AND CODING, https://www.medicalbillingandcoding.org/using-cpt/ (last visited Dec. 6, 2020). Alternatively, some CPT Codes typically are not billed together because even though each Code involves a scan of roughly the same body parts, the CPT Manual precludes "'double dipping" for component services nominally described in two Codes. That is, each code requires a separate

physician order. *See United States v. Fadul*, No. CIV.A. DKC 11-0385, 2013 WL 781614, at *2 (D. Md. Feb. 28, 2013).

It also appears that failing to reasonably interpret the CPT Manual can lead to criminal conviction under the False Claims Act even though the CPT Manual's standards are not subject to constitutional vagueness challenges. *See United States v. Janati*, 237 F. App'x 843, 846 (4th Cir. 2007). Stated differently, even though the CPT Manual's instructions are not "laws" that must survive Due Process Clause challenges, one can still be criminally liable for knowingly misusing the CPT Codes. This is because the law that is alleged to be violated is the False Claims Act, not the CPT Manual. The False Claims Act prohibits falsely billing Medicare. So, it stands to reason that if one agrees to use the CPT Codes to bill Medicare, one must meet all the requirements set forth by the CPT Manual. If one does not, it is the False Claims Act that is violated, not the CPT Manual. *Cf. id.* at 847 ("Any opacity of the CPT manual would have to be so great that one could not *know* the proper code and therefore could not *knowingly* record an improper code.") (emphasis in original).

So, a provider can be liable for falsely certifying that it has completed the requirements for billing a particular CPT Code. PVA argues that it made no such false certification. It asserts that a separate written report is only required when the physician performs the professional component of a vascular study, but not the technical component. ECF No. 112 at 11. PVA asserts that this is clear from the text of the CPT Manual, which states: "The physician's interpretation of the results of diagnostic tests/studies (i.e., professional component) with preparation of a separate distinctly identifiable signed written report may also be reported separately, using the appropriate CPT® code with modifier 26 appended." ECF No. 112 at 11 (citing ECF No. 95 at 11). The question,

then, is whether a separate, written report is always required when billing for the professional component of a vascular study—whether separately or globally.

The CPT Manual's Radiology Guidelines, which expressly cover diagnostic ultrasounds, states "All imaging guidance codes require: (1) image documentation in the patient record and (2) description of imaging guidance in the procedure report. All [radiological supervision and interpretation] codes ***require***: (1) image documentation in the patient's permanent record and (2) a procedure report or separate imaging report that ***includes written documentation of interpretive findings of information contained in the images and radiologic supervision of the service***." ECF No. 95 Ex. 45 at 475 (emphasis added). That same page later states "A written report (e.g., handwritten or electronic) signed by the interpreting individual should be considered an integral part of a radiologic procedure or interpretation." *Id.* Further, the Medicare Claims Processing Manual, Chapter 13 – Radiology Services and Other Diagnostic Procedures, in section 20.1, entitled "Professional Component (PC)" states, "The interpretation of a diagnostic procedure includes a written report." ECF No. 113 Ex. 37 at 425. From this it appears that a written report is required when using any radiological imaging Code, including the global CPT Code for vascular ultrasounds.

Other parts of the CPT Manual reiterate the need for a written report when separately billing for the professional component of a vascular ultrasound. The Manual later states that "[u]se of ultrasound, without thorough evaluation of organ(s) or anatomic region, image documentation, and final, written report, is not separately reportable." ECF No. 95 Ex. 45 at 495. Thus, a written report is required when a provider bills Medicare for the professional component of a vascular study. PVA does not dispute this. ECF No. 112 at 11–12 (stating that portions of the CPT Manual describe "what the AMA recommends for physician interpretation of vascular studies when the

physician or physician group does not perform the technical component of the study."). But PVA's assertion that a separate written report is only required when billing separately for the professional component is undercut by the CPT Manual's insistence that a "procedure report or separate imaging report that includes written documentation of interpretive findings" is required for "all RS&I codes." ECF No. 95 Ex. 45 at 475. Thus, a written report is required to bill the professional component generally, whether separately or globally.

Relators' assertion here is not that the CPT Codes always require a *separate* report. Relators assert only that a written report must be generated before billing the professional component. ECF No. 95 at 12–14. Relators claim that 69,178 of PVA's charges are false because of the particular circumstances of those charges. That is, PVA only included the physicians' interpretations of the vascular studies associated with each of these charges in MedStreaming or in the patients' E/M visit notes. *Id*. at 13–14 (citing Dr. Alsabrook Dep. Tr. at 94:2-16 (testifying that there is nowhere that PVA would document a physician's interpretation of a patient imaging study other than an E/M note or MedStreaming)). But for the Testing Only patients there was no E/M visit note, so the only place a written report could have been generated was in MedStreaming. *Id*. at 14 (citing ECF No. 95 Ex. 10, Hembling Dep. Tr. at 32:20-33:11; Ex. 2, Burrow Dep. Tr. at 29:24–30:9; ECF No. 95 Ex. 3, Gilpin Dep. Tr. at 57:15–23; ECF No. 95 Exs. 53, 74–195). As mentioned, Relators assert that no MedStreaming report was ever generated for this tranche. As for the Double Billing patients, Relators argue that PVA would have submitted false claims even if PVA included the physicians' interpretations in the E/M visit notes because the CPT Manual prohibits that practice. *Id*. (citing ECF No. 95 Exs. 45, 55, 197, 204–205; ECF No. 95 Ex. 4, Britt Dep. Tr. at 126:25–127:13; Ex. 7, July 23, 2020 Dep. Tr. of PVA expert Melissa Scott, CPC, CHC, CHIAP at 81:21–82:5; Scott Dep. Exs. 5–14). Thus, the argument goes, because one of the only

two places where PVA includes a physician's interpretation of a vascular study is not available, PVA's certification that it completed the professional component would be false unless it included the physicians' interpretations in MedStreaming. *Id*.

This begs the question of whether the CPT Manual actually prohibits PVA's practice of including the physicians' interpretations in the E/M visit notes. As mentioned, the CPT Manual states "the physician's interpretation of the results of diagnostic tests/studies (i.e., professional component) *with preparation of a separate distinctly identifiable signed written report* may also be reported separately, using the appropriate CPT® code with modifier 26 appended." ECF No. 95, Ex. 45, at p. 6 (emphasis added). PVA's response is summed up by their expert witness, Melissa Scott:

> The guidance specifies that when a physician does not render both the technical and professional components, the interpretation of the diagnostic test (professional component only) may still be separately billable when supported by a written report. What the guidance does not state is that in the context of an evaluation and management service, there should be a stand-alone report. It simply states that in the absence of a technical component, the interpretation must be documented in written report to be supported.

ECF No. 112 at 12 (citing Scott Expert Report, ¶ 77).

One industry publication, titled "Medical Documentation Requirements: Diagnostic Urologic Ultrasound and Ultrasound-Guided Procedures," indicates that including a physician interpretation of a vascular study in the patient's medical chart is permissible in some circumstances. ECF No. 95-6 at 14 ("The minimum documentation required by CPT® is a separate summarized written paragraph documented in the patient's chart"). However, under the caption "Imaging Performed on the Same Day as an Encounter," the article states "The American Medical Association clarified that if an imaging test is performed on the same day as an Evaluation & Management (E&M) service, that each should be separately documented and billed, as stated in

the E&M Services Guidelines Section in the CPT® book." *Id*. at 15. The article posits that this interpretation is consistent with other sections of the CPT Manual, which state that CPT Codes for radiological imaging in other contexts "require image documentation and radiological supervision, interpretation, and report services require a separate interpretation." *Id*. Relators highlight many other industry publications that appear to support their theory. ECF No. 95 App. No. 75 (collecting industry publications).

The Court agrees with the Relators' and industry's interpretation of the CPT Manual. The first sentence of the cited section—"The actual performance and/or interpretation of diagnostic tests/studies ordered during a patient encounter are not included in the levels of E/M services"—indicates that E/M Services and diagnostic studies should be billed separately. The following sentence—"Physician performance of diagnostic tests/studies for which specific CPT® codes are available may be reported separately, in addition to the appropriate E/M code"—indicates that when a diagnostic study has been performed, it can be billed separately in addition to an E/M code. The Court reads the use of the permissive "may" not as bestowing an option, but as highlighting a possibility that need not always have occurred—*i.e*., that a diagnostic study was performed, as opposed to another service. The final sentence highlights the fact that the professional component may also be billed separately. Its reference to the separate report appears to simply reiterate the requirements of billing for the professional component. The Court does not agree with PVA's reading of the CPT Manual.

Relators' Wrong Provider tranche of allegedly false charges needs no meticulous analysis. Submitting bills to Medicare that represent the wrong rendering physician is plainly a false claim. *See United States v. Mackby*, 261 F.3d 821, 826 (9th Cir. 2001) ("a claim may be false even if the services billed were actually provided, if the purported provider did not actually render or

supervise the service."); *see also Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975). The Medicare Program Integrity Manual provides a list of "Examples of Medicare Fraud," which includes "[m]isrepresenting dates and descriptions of services furnished or the identity of the beneficiary or the individual who furnished the services." ECF No. 95 Ex. 205, § 4.2.1. Any bills submitted under the name of a physician who did not render the services described therein are false.

In sum, the conduct alleged by the Relators constitutes a fraudulent course of conduct under the False Claims Act.

C. Fact issues remain on materiality.

For a false claim to violate the FCA, it must be material. The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). The Fifth Circuit has held that the FCA requires "proof only that the defendant's false statements could have influenced the government's pay decision or had the potential to influence the government's decision, not that the false statements actually did so." *U.S. ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 661 (5th Cir. 2017). The Supreme Court clarified the scope of the materiality requirement, emphasizing "that the False Claims Act is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations." *Universal Health Servs., Inc. v. United States ("Escobar")*, 136 S. Ct. 1989, 2004 (2016). The Court stated:

> The materiality standard is demanding. The False Claims Act is not 'an all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial. In sum, when evaluating

> materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive.
>
> Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 2003–04.

PVA argues that Relators have not satisfied the *Escobar* standard. ECF No. 94 at 22; ECF No. 112 at 19. It asserts that Relators have demonstrated no prior instance in which the Government has declined to pay a particular type of claim despite knowledge that certain requirements were violated. ECF No. 94 at 23. Contrarily, PVA argues that the Government's continuing payments to PVA despite knowledge of PVA's billing practices is "strong evidence that the requirements are not material." *Id*. (citing *Escobar*, 136 S. Ct. at 2003–04). It posits, "The Government's continual lack of any action is more than enough to show that Relators cannot satisfy their burden of proving the FCA's 'demanding' and 'rigorous' materiality requirement." *Id*. at 26.

In support of this contention, PVA offers the declaration of Katherine Britt, Vice President of Operations at PVA. ECF No. 94-2. Britt attests that the HHS issued a subpoena to PVA on June 19, 2018, for medical and business records. *Id*. ¶¶ 30, 31; *see also* ECF No. 94 Ex. 10 (HHS Subpoena Duces Tecum). PVA produced more than 50,000 pages of documents, including 414 patient files. *Id*. ¶ 32. PVA representatives, including Britt, met with members of the HHS Office of Inspector General and Department of Justice attorneys to discuss the production. *Id*. ¶ 33. Despite its transparency and compliance with the Government's investigation, Britt asserts that no

Government agency has ever demanded a return of federal funds for allegedly false bills. *Id*. ¶ 34. Relators do not dispute that the Government investigated the alleged false billing and declined to intervene.

Relators respond that PVA's false certification that it completed the professional components of the vascular studies is material. In support, Relators highlight the CMS manual entitled "Medicare Fraud & Abuse: Prevent, Detect, Report," which states that "billing for services not provided" is an example of an improper claim. ECF No. 95, Ex. 204, at 11. They further point out that the conduct alleged is included among the Medicare Program Integrity Manual's "Examples of Medicare Fraud." ECF No. 95 at 32–33 (citing Ex. 205, § 4.2.1).

Although the Government declined to intervene in this case, it submitted a Statement of Interest, as is its prerogative. In it, the Government argued that its declination to intervene in the case is irrelevant to the materiality analysis. ECF No. 113 at 5 (citing *U.S. ex rel. Chandler v. Cook Cty., Ill*., 277 F.3d 969, 974 n.5 (7th Cir. 2002), *aff'd*, 538 U.S. 119 (2003) and *United States ex rel. Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 455 (5th Cir. 2005)). This proposition logically flows from the structure of the FCA, which expressly permits *qui tam* lawsuits in which a private citizen proceeds on behalf of the United States. The Government also argues that continued payment by a federal agency is not dispositive of materiality either. *Id*. at 7. This is because the Court in *Escobar* stated that "actual knowledge that certain requirements were violated" is predicate to the proposition handed down therein. *Id*. (citing *Escobar*, 136 S. Ct. at 2003). That is, continued payment is only "strong evidence" of immateriality if Medicare actually knew that false claims were being submitted.

And that makes sense. There are simply too many possible explanations for an agency's action or inaction to impute a decision on the merits of an allegation of fraud unless it is clear that

the agency has actual knowledge of fraud. It is not enough that the agency is aware of allegations of fraud, it must be aware of the fraud itself. The First Circuit held precisely this way in *Escobar* on remand. *See Universal Health Servs., Inc. v. United States ("Escobar II")*, 842 F.3d 103, 111–12 (1st Cir. 2016) ("mere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance"). So, the Court is not in a position to conclude outright that the Government has made a determination that the fraudulent conduct alleged is not "material" as defined by the FCA. As this Court has recently held, "There is no *per se* rule; continued payment is only relevant to the extent that it is probative of materiality." *United States ex rel. Campbell v. KIC Dev., LLC*, No. EP-18-CV-193-KC, 2019 WL 6884485, at *10 (W.D. Tex. Dec. 10, 2019) (citing *Trinity Indus. Inc.*, 872 F.3d at 663–64).

It is important to clarify what the Government's inaction here actually is. The Government's declination to intervene does not indicate a decision was made by the Government that Relators' claims must fail. Importantly, PVA provides no evidence that Medicare actually knew that PVA was submitting false claims. That the Government conducted an investigation is certainly probative of materiality, but without evidence of actual knowledge, the Court cannot apply the strong presumption of immateriality highlighted by *Escobar*. Thus, the Government's inaction is probative, but not dispositive on this issue.

PVA is correct that Medicare's continued payment of claims submitted by PVA is evidence that PVA's actions are not material under the *Escobar* standard. However, that evidence is contradicted by Medicare and CMS' own statements that billing for services not provided are examples of fraud. *See* ECF No. 95, Ex. 205, § 4.2.1 One of the reasons that the Government's decision to continue to make payments on allegedly fraudulent claims is "relevant, but not automatically dispositive," *Escobar*, 136 S. Ct. at 2003–04, is that the Court cannot speculate about

what information the Government actually knows, especially in Medicare fraud lawsuits in which the Government has declined to intervene.

Healthcare administration is complicated. "The Government does not enjoy the luxury of refusing to reimburse health care claims the moment it suspects there may be wrongdoing." *United States v. Berkeley HeartLab, Inc.*, No. 14-cv-230, 2017 WL 4803911, at *7 (D.S.C. Oct. 23, 2017). Thus, the Government's continued payment despite knowledge of Relators' allegations does not necessarily imply immateriality. It is equally likely that Medicare saw value in continuing to reimburse PVA for its services until the legality of its actions could be properly adjudicated. The Court considers evidence of the Government's declination to intervene only insofar as it is probative as described by *Escobar*. Relators' objections to this evidence are overruled. *See* ECF No. 107-2.

Relators and PVA have each provided evidence that could reasonably be construed to favor their materiality arguments. The Fifth Circuit commands the Court not to weigh this evidence. *See Deville*, 567 F.3d 163–64. As long as a jury can reasonably return a verdict in favor of either party, a genuine issue of material fact exists and the Court cannot grant summary judgment. The Court finds that fact issues exist as to whether the alleged false bills were material to the Government's reimbursement decision.

However, the Court finds that there is no genuine issue of material fact as to the materiality of claims that encompass the Wrong Provider Tranche. Strong evidence shows that the Government probably would not have reimbursed PVA for claims which listed the name of a physician who did not render the services described therein had it known such claims had been submitted. As Relators point out, the Medicare Program Integrity Manual's list of "Examples of Medicare Fraud" include "Misrepresenting . . . the identity of the beneficiary or **the individual**

who furnished the services." ECF No. 95 at 32–33 (citing ECF No. 95 Ex. 205 § 4.2.1) (emphasis added). That this particular conduct is listed as an example of Medicare fraud is telling. CMS uses less forceful language in its CMS Manual when it provides a list of "[e]xamples of **improper** claims." *See* ECF 95 Ex. 204 at 11 (emphasis added). Put simply, identifying conduct as "fraud" as opposed to "improper" implies a greater level of culpability associated with that conduct. This language from CMS, viewed in conjunction with American courts' understanding that the submission of claims under the wrong physician's name generally leads to FCA liability, *see Mackby*, 261 F.3d at 826, leads the Court to conclude that the Government would not have paid these claims if it knew of their falsity. Accordingly, summary judgment is granted to Relators on the issue of materiality only as to the claims that encompass the Wrong Provider Tranche. Both parties' motions for summary judgment are denied as to the issue of materiality on the remainder of the Relators' claims.

D. Relators have proven that PVA acted with scienter.

The FCA imposes liability on "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." *See* 31 U.S.C. § 3729(a). The FCA defines "knowingly" as not only "actual knowledge" of information, but also "deliberate ignorance" or "reckless disregard of the truth or falsity of the information," even when there is no "proof of specific intent to defraud." *Id*. § 3729(b)(1). When "state of mind is an essential element," "it is less fashionable to grant summary judgment." *Int'l Shortstop, Inc. v. Rally's, Inc.*, 939 F.2d 1257, 1265 (5th Cir. 1991). But the "presence of an intent issue does not automatically preclude summary judgment; the case must be evaluated like any other to determine whether a genuine issue of material fact exists." *Guillory v. Domtar Indus., Inc*., 95 F.3d 1320, 1326 (5th Cir. 1996). Summary judgment is proper under the FCA where the defendants "either purposefully, or with

reckless disregard to the truth or falsity of their statements, misled" the Government. *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458 (5th Cir. 2009). As relevant here, no genuine issue of material fact exists when "there is no plausible reading of the CMS Manual that could support the defendants' billing practices." *United States ex rel. Drummond v. BestCare Lab. Servs.*, L.L.C., 950 F.3d 277, 281 (5th Cir. 2020).

Relators argue that both Medicare and industry publications make clear that PVA's practices were improper. There is no reasonable explanation for PVA's failure to understand that no other healthcare providers utilized similar billing practices. Further, Relators detail an attempted change to PVA's billing practices intended to "allow[] for compliance," but abandoned when it realized that the change would affect revenue. ECF No. 95 at 17 (citing App. Nos. 16, 46, 47, 79). As outlined above, PVA's practice was to bill Medicare regardless of whether a PVA Physician had completed a written report. *See* Part III.B, *supra*. Relators assert that PVA knew that this practice was improper and tried to change it. ECF No. 95 at 17. In 2017, PVA embarked on a "compliance project" in which it attempted to change this practice. *Id*. On February 8, 2017, PVA's Vascular Lab Committee identified three motives for its "transition to billing after studies are read." *Id*. (citing ECF No. 95 Ex. 31 at DEF007698). The motives were to (1) "Ensure billed to appropriate physician," (2) "Ensure no audit requests for incomplete medical records," and (3) "Allow for docs to read each others stuff." *Id*.

To achieve these goals, PVA made attempts to require billing Medicare only after interpretations and reports were completed and decreasing the delays in physician interpretation. *Id*. The meeting minutes from an April 5, 2017 PVA Vascular Lab Committee meeting describe these changes as an attempt to "Allow[] for Compliance," by "billing after study interpreted." *Id*. at 17–18 (citing ECF No. 95 Ex. 32 at DEF007691). Relators also cite a document that Barbara

Burrow, PVA's Technical Director, sent to Brian Hembling entitled "Vascular Lab Billing/Coding" which states "[t]he billing/coding process was changed this year. It is now required for a study to have a completed report to be signed and read before it is billed." ECF No. 95, Ex. 31 at DEF007085. That same document indicates that PVA Physicians would be required to bill for a vascular study within five days of completion, and that "read groups" would be created because "Physicians were having issues reading reports in a timely fashion." *Id*. at DEF 007085–86. Relators also cite an email from Barbara Burrow to all PVA Physicians stating studies which have not been read for over 48 hours after generation would be reassigned to the read group. ECF No. 95 Ex. 30. Finally, Relators cite portions of Burrow's deposition, in which she says that her "understanding is that for a time we thought that we needed to have the study interpreted before it was billed. . . . before [2016] we were not in the understanding that we had to have a report completed in MedStreaming to bill for it." ECF No. 95 Ex. 2, Burrow Dep. Tr. at 143:21–144:14.

Problems quickly arose. Relators assert that PVA feared the changes would result in a "35% change in vascular lab office related revenue." ECF No. 95 at 18 (citing Ex. 32 at DEF007698). PVA had trouble getting physicians to read studies on time. *Id*. (citing Ex. 32 at DEF007703–04). By June, PVA reverted to its previous practice of billing when the vascular study was in "QA" status—before it had been interpreted. *Id*. (citing Ex. 32 at DEF007700 ("Coding Process Changed; Changed again; Now study only set to QA, then charged / billed.")). Thus, the short-lived attempt at compliance came to an end.[2]

PVA responds that whether it attempted to alter its billing practices has "zero bearing on whether a false claim was submitted." ECF No. 112 at 14. This is because, according to PVA,

[2] Relators also cite internal e-mails from before PVA started using MedStreaming, which appear to indicate that Burrow knew that vascular studies could not be billed until after interpretation. ECF No. 95 at 18–19 (citing ECF No. 95 Exs. 12 and 14).

Relators are required to show that a particular individual knew the practices were improper, and collective action cannot suffice. *Id*. at 17 (citing *U.S. ex rel. Ruscher v. Omnicare, Inc*., No. 4:08-CV-3396, 2015 WL 5178074, at *29 (S.D. Tex. Sept. 3, 2015), *aff'd sub nom*. *U.S. ex rel. Ruscher v. Omnicare, Inc*., 663 F. App'x 368 (5th Cir. 2016)). It then asserts that even though no official compliance policies are required by Medicare, PVA's use of comprehensive compliance procedures indicate that PVA did not act with reckless disregard or deliberate ignorance as to the propriety of its practices. *Id*. at 18.

PVA further asserts that its interpretation of the CPT Manual was reasonable, and there can be no summary judgment where a statute or regulation is subject to multiple reasonable interpretations. *Id*. at 15 (collecting cases). PVA's final argument is that it only performed 9,458 vascular studies without generating a report, accounting for only 4.9% of its business. ECF No. 94 at 21. "An error rate that low," it asserts, "does not support an argument that PVA engaged in a fraudulent scheme to cheat the Government, and, in fact, supports the opposite conclusion." *Id*. (citing *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1034 (D. Nev. 2006)).

The cases that PVA cites in support of its proposition that no summary judgment can be had where the defendant's interpretation of a statute or regulation is reasonable do not control here. The point is simple; the applicable statute is the FCA, which unambiguously commands all government contractors not to submit false claims. The only reasonable interpretation of the FCA is that it prohibits the submission of false claims to the federal government. However, the principle that scienter is not satisfied where a defendant acted reasonably still stands. So, if the evidence that PVA provides indicates that its interpretation was reasonable, summary judgment must fail.

But PVA provides no evidence. PVA points to no concrete evidence that it was under the impression that its actions were proper. The only argument that PVA makes that might prevent

summary judgment on this issue is whether it was reasonable, even if incorrect, for PVA to believe it did not need to generate a written report prior to billing Medicare. ECF No. 112 at 15. But its argument is simply that there is no requirement of such a written report. As described above, that is not true. For an interpretation to be reasonable, it must actually be held. *See Matsushita Elec. Indus. Co.*, 475 U.S. at 586–87 (1986) (The nonmoving party "must do more than simply show that there is some metaphysical doubt as to the material facts."). There is simply no indication that PVA actually held that the belief that its interpretation was legal and correct.

Relators, on the other hand, have provided substantial evidence to support their scienter argument. In fact, most of the evidence comes from PVA's own Technical Director and member of the Vascular Lab Committee, Barbara Burrow. The Fifth Circuit has recognized that it is difficult to grant summary judgment on a claim in which scienter is an essential element. Even though a court may grant summary judgment when the intent element is clearly met, those cases are few and far between. For example, the case relied on by Relators, *Drummond*, was one of the rare cases in which the defendants were clearly billing for services not rendered, and no reasonable interpretation of regulatory guidance could support the defendants' position. In that case, the defendants were submitting claims for travel expense reimbursement when no personnel had actually traveled. *United States ex rel. Drummond v. BestCare Lab. Servs*., L.L.C., 950 F.3d 277, 281 (5th Cir. 2020). That is a clear-cut violation of the FCA.

The issue is more complex in this case. Relators must prove that PVA acted with at least "deliberate ignorance" or "reckless disregard" of the truth or falsity of the information that it submitted to Medicare. Although the widespread industry publications supporting Relators theory are strong evidence that PVA recklessly disregarded industry practice, it is not necessarily the case that PVA knew that its practices were fraudulent. The strongest evidence offered by Relators is

the evidence indicating that PVA was not reading vascular studies before billing for them. Relators provide evidence that suggests that at least some staff at PVA knew that studies needed to be interpreted prior to billing for those claims. In 2014, when PVA started using MedStreaming, it stopped focusing on the timing of the interpretation and was billing prior to interpretation. This practice continued until 2017, when PVA began a process of changing its regulatory compliance policies to require interpretations be completed prior to billing Medicare. However, PVA abandoned this policy change when it realized that about a third of its revenue would not come in as quickly as it did under the current practice. PVA then continued billing prior to reading vascular studies. This scheme described by Relators strongly suggests that PVA knew its practices skirted the line of compliance, and declined to get back into compliance when it realized that revenues would drop if it did so. Additionally, PVA does not dispute that it used a "pool" rendering system that it knew allowed MedStreaming reports to occasionally be signed by physicians who did not perform the professional component of the vascular study. *See* Part III.B, *supra*.

The Court holds that PVA has not established that there is no genuine dispute as to any material fact and it is entitled to judgment as a matter of law on this issue. The Court further finds that, even construing all reasonable inferences in PVA's favor, *Deville*, 567 F.3d at 163–64, Relators have proffered evidence demonstrating that PVA knew that it was submitting claims for reimbursement to Medicare when it had not fully furnished the services it certified it had completed. At the very least, PVA acted with "deliberate ignorance" or "reckless disregard of the truth or falsity of the information" it was providing to Medicare. 31 U.S.C. § 3729(b)(1). Accordingly, the Court GRANTS summary judgment to Relators on the issue of scienter.

E. Whether PVA's claims caused the government to pay significant monies.

The Court turns to the proof offered by the Relators and the contradictory evidence proffered by PVA. Relators have the burden of showing that the defendants submitted false claims, but Relators are not required to provide direct evidence of each instance of fraud. "On the contrary, courts regularly find liability where—as here—relators provide circumstantial evidence that shows defendants engaged in a fraudulent scheme and submitted claims to Medicare seeking payment of such fraudulent claims." *Waldmann*, 259 F. Supp. 3d at 609; *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 192 (5th Cir. 2009). After establishing FCA liability, a relator can base damages calculations on statistical "sampling and extrapolation." *United States v. Vista Hospice Care, Inc.*, No. 3:07-CV-00604-M, 2016 WL 3449833, at *12, n.100 (N.D. Tex. June 20, 2016) (citing *United States v. Fadul*, 2013 WL 781614, at *14 (D. Md. Feb. 28, 2013)). Statistical sampling can be particularly valuable in the medical fraud context. *See, e.g. United States v. Krizek*, 192 F.3d 1024, 1030–31 (D.C. Cir. 1999); *see also U.S. ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 714 (7th Cir. 2014) ("there has to be some evidence—statistical or otherwise—from which the jury could determine (at least approximately) how many of [defendant's] documents contained false certifications.").

PVA argues that Relators have failed to carry their burden of production of evidence showing that PVA double billed Medicare. ECF No. 112 at 10. It asserts that Relators' expert witness Church did not review the medical records necessary to determine whether PVA improperly billed for E/M Services in conjunction with a vascular study. *Id.* at 10–11 (Ex. B, Church Depo. 118:3-17; Docs. 83 & 102). A mere passing glance at the cited portion of Church's testimony reveals that Church was not retained to conduct a factual statistical analysis for Relators. Indeed, after Church admitted that he did not review medical records to determine whether PVA had actually improperly billed Medicare, he added, "Reviewing medical records is outside the

scope of my work." ECF No. 112 Ex. B, Church Depo. 118:18–19. PVA cites no other affirmative evidence showing that Relators' description of its billing practices is factually incorrect.

Relators proffered the report of statistician Dr. Zachary Nye, which contains Dr. Nye's analysis of PVA's billing data. ECF No. 94 Ex. 200. Dr. Nye's report asserts that it relied on PVA "Medical Records Data," "Billing System Data for Imaging," and "Billing System Data for E/M Services," each of which are defined in the report. *Id*. at 2–3. Relators charged Dr. Nye with identifying "instances when PVA posted a charge in its Billing System Data for Imaging prior to the completion date of the associated 'final report' (*i.e.*, what Plaintiffs allege to be a 'False Billing')." *Id*. at 3. Dr. Nye's analysis found 69,178 instances of such false billing out of 285,481 charges billed, amounting to a falsity rate of 24.2%. *Id*. at 4. Of that figure, 2,094 instances of falsity fall within the Wrong Provider Tranche and 11,728 instances of falsity fall into the Testing Only Tranche described above. *Id*. at 5. Dr. Nye calculated that these false bills resulted in a total of $8,288,590 in payments. *Id*. Not all of this money was paid by the federal government, however. Exhibit 4a.i in Dr. Nye's supplemental report breaks down the total charges and payments made for false billings by payor. The scope of the FCA does not reach the payments received from private insurance companies that are included in this report.

PVA attempts to contradict Relators' evidence in the form of a "Response to Relators' Appendix" attached as Exhibit A to PVA's response to Relators' Motion for Summary Judgment. *See* ECF No. 112-1. In its response, PVA objects to the admissibility of Dr. Nye's expert report as improper hearsay, and for the reasons rejected above. *Id*. ¶ 26. PVA admits that "the professional component of vascular studies was billed before a MedStreaming report was signed for some services," but does not present evidence refuting Dr. Nye's analysis. *Id*. ¶ 27.

"[O]n a motion for summary judgment, the evidence proffered by the plaintiff to satisfy his burden of proof must be competent and admissible at trial." *Bellard v. Gautreaux*, 675 F.3d 454, 460 (5th Cir. 2012) (citing *Martin v. John W. Stone Oil Distrib., Inc.*, 819 F.2d 547, 549 (5th Cir.1987)). Relators did not argue that Dr. Nye's report is admissible under any exception to the hearsay rule. However, the Court notes that there is a possibility that Dr. Nye's report could be admissible under Rule 1006 of the Federal Rules of Evidence, which permits the use of "a summary, chart, or calculation to prove the content of voluminous writings, recordings, or photographs that cannot be conveniently examined in court." FED. R. EVID. 1006. Dr. Nye's report and accompanying exhibits comprise hundreds of pages of spreadsheets summarizing Dr. Nye's analysis. Even so, there has been no argument on the issue of whether the evidence underlying Dr. Nye's report is admissible—a necessary step in the FRE 1006 analysis. *Bannum, Inc. v. United States*, 59 Fed. Cl. 241, 244–45 (2003). The Court will defer ruling on the admissibility of Dr. Nye's report until trial.

As is often the case in lawsuits that involve expert analysis, PVA may call its own expert witnesses to refute Dr. Nye's analysis. As noted in Part II.A, *supra*, the Court has excluded the portions of Dr. Scott's report that rebut Dr. Nye's opinions, but PVA can offer other expert analysis to refute Dr. Nye's findings. *See e.g.*, ECF No. 94 Ex. 203 (Expert Report of Dr. Collier).

PVA can also provide non-expert testimony to refute Relators' claims. For example, PVA offered the declaration of Brian Puente, PVA's IT Director. ECF No. 94-7. Although Mr. Puente fails to explain in detail the methodology he relied upon, he attests that he examined PVA's Allscripts PM data and found that out of 194,886 relevant billable vascular studies, 9,458 studies did not have an E/M visit within 14 days after the date that the study was performed. *Id.* ¶¶ 4–7. Relators object that Puente is improperly providing expert testimony and was not disclosed as a

non-retained expert under Rule 26(a)(2)(c). ECF No. 107-3. The Court declines to rule on those objections because the Court is merely highlighting that PVA can provide testimony from PVA employees establishing fact issues as to the number of false claims submitted.

The Court finds that Relators have proffered reliable and valid statistical evidence from which a jury could determine by a preponderance of the evidence the number of false claims submitted by PVA. However, a fact issue exists as to the number of false claims actually submitted and the amount of money paid by the Government. Accordingly, the Court denies each party's motion for summary judgment on this issue.

F. PVA's Constitutional arguments fail as a matter of law.

PVA's final argument is that Relators' pursuit of non-intervened FCA claims is unconstitutional. Specifically, PVA argues that a private individual bringing a non-intervened FCA claim violates the Appointments Clause and Separation of Powers. ECF No. 112 at 24. The Court rejects this argument as clearly contradictory to existing Fifth Circuit precedent. *See Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749 (5th Cir. 2001).

CONCLUSION

As explained herein, the Court finds that Relators have provided legally sufficient evidence to overcome PVA's motion for summary judgment. The Court finds that a healthcare provider's submission of the CMS-1500 form certifying that it had rendered the services described therein is legally and factually false when a separate written report depicting a physician's interpretations has not been completed. The Court also finds that PVA acted knowingly, with deliberate ignorance, or with reckless disregard for the truth or falsity of the information provided when it submitted the CMS-1500 form certifying that it had completed the professional component of a vascular studying when it had not done so. The Court finds that the claims described in the Wrong

Provider Tranche were materially false under the False Claims Act, but that there is a genuine issue of fact as to whether the submission of the remaining false claims was material to the Government's payment decisions. Finally, the Court finds there is a genuine issue of fact as to whether the Government paid significant money on the alleged false claims, and that the trier of fact could determine by a preponderance of the evidence the number and amount of claims that PVA submitted that were rendered false by the conduct that Relators describe.

Accordingly, the Court hereby **ORDERS** that:

Relators' Motion to Strike or Exclude Certain Opinions of Melissa Scott, CPC, CHC, CHIAP (ECF No. 80) is hereby **GRANTED**. Furthermore,

Defendant Peripheral Vascular Associates, P.A.'s Motion to Exclude the Testimony of Dr. James Alexander (ECF No. 82) is hereby **DENIED**. Furthermore,

Defendant Peripheral Vascular Associates, P.A.'s Motion to Exclude the Testimony of Robert D. Church, Jr. (ECF No. 83) is hereby **DENIED**. Furthermore,

Defendant Peripheral Vascular Associates, P.A.'s Motion to Exclude the Testimony of Dr. Zachary Nye (ECF No. 86) is hereby **DENIED**. Furthermore,

Defendant Peripheral Vascular Associates, P.A.'s Motion for Summary Judgment (ECF No. 94), is hereby **DENIED**. Furthermore,

Relators' Motion for Summary Judgment (ECF No. 95) is **GRANTED IN PART** as to the issues of falsity, materiality with regard to the Wrong Provider Tranche, and scienter, and **DENIED IN PART** as to the other issues of materiality and payment.

It is so **ORDERED**.

SIGNED this 14th day of December, 2020.

XAVIER RODRIGUEZ
UNITED STATES DISTRICT JUDGE